DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 2, 2015

Pinhu Sama Medical Packing Co., Ltd.
% Mr. Ray Wang
Official Correspondent
1-202, Build 3, Beijing New World
No.5 Chaogyang Rd., Chaogyang District
Beijing, 100024 CN

Re: K150227
Trade/Device Name: Disposable Blood Pressure Cuff Guard
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: January 30, 2015
Received: February 2, 2015

Dear Mr. Ray Wang,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): __K150227___

Device Name: __Disposable Blood Pressure Cuff Guard____

Indications For Use:

This device has the potential to reduce or prevent patient to patient cross contamination which can occur during blood pressure measurement procedures, for single patient use only. It covers a blood pressure cuff to provide a barrier between patient and cuff.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _K150227_

1. Date of Preparation:2015/1/30

2. Sponsor Identification

PINGHU SAMA MEDICAL PACKING CO., LTD.
1 Qunfeng Road, South of Lindai, PingHu, Zhejiang, 314202, China

Establishment Registration Number: 3010521050

Contact Person: Ma JianZhong
Position: General Manager
Tel: +86-573-85923333
Fax:+86-573-85924444
Email: mjz1966@163.com

3. Designated Submission Correspondent

Mr. Ray Wang

Beijing Believe Tech. Service Co., Ltd

Tel: +86-21-50313932,
Fax: +86-21-68093116
Email: Ray.Wang@believe-med.com

4. Identification of Proposed Device

Trade Name: Disposable Blood Pressure Cuff Guard
Common Name: Blood Pressure Cuff Cover
Model(s): S, M, L

Regulatory Information

Classification Name: Blood Pressure Cuff
Classification: 2
Product Code: DXQ
Regulation Number: 870.1120
Review Panel: Cardiovascular

Intended Use Statement:
This device has the potential to reduce or prevent patient to patient cross contamination which can occur during blood pressure measurement procedures, for single patient use only. It covers a blood pressure cuff to provide a barrier between patient and cuff.

Device Description
This device is a cover for blood pressure cuffs. It is made of polyethylene coated on Tyvck. Blood pressure cuffs are used throughout the healthcare industry as a means of monitoring patient blood pressure. Because blood pressure cuffs are used on multiple patients there is a concern about cross contamination.

When the blood pressure cuffs become contaminated they should be cleaned. A blood pressure cuff Guard can reduce the need to clean blood pressure cuffs.

In order to address the cross contamination issue for blood pressure cuffs a blood pressure cuff Guard has been designed. The product is a non-sterile, clean, ready to use sleeve that is applied between the patient arm and the blood pressure cuff. The cuff Guard has the potential to reduce transfer of patient contamination to the cuff and from the cuff to the patient.

The blood pressure cuff Guard is a single patient product designed to survive average use during an average hospital stay. If the blood pressure cuff Guard becomes contaminated, soiled or torn during this time it would be replaced with a new blood pressure cuff Guard.

The blood cuff Guard has a two layer structure. The inner layer is made of Tyvck. The outer layer is made of cast film of polyethylene.

The polyethylene is a fluid repellent, and is resistant to microbial penetration, thus provides a barrier between the blood pressure cuff and patient.

The whole guard is approximately 20 μm thick and is available in various different length and

width.

The guard is designed as pouchlike with one open, the blood pressure cuff can be packed into it and sealed with adhesive tape, and which can be secured around the patient arm by two velcro. The adhesive tapes are located at the edge of open and the Velcro located at the two ends of outer guard, both of them are not contact with the patient skin.

5. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K141998
Product Name: SAMA Disposable Blood Pressure Cuff Barriers
Model Name: Pinghu Sama Medical Packing Co., Ltd.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- Bench Testing for the performance of Dimensions, Adhesive Tape, Compatibility with BP Cuff and Velcro.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device	Remark
Intended Use	This device has the potential to reduce or prevent patient to patient cross contamination which can occur during blood pressure measurement procedures, for single patient use only. It covers a blood pressure cuff to provide a barrier between patient and cuff.	This device has the potential to reduce or prevent patient to patient cross contamination which can occur during blood pressure measurement procedures, for single patient use only. It covers a blood pressure cuff to provide a barrier between patient and cuff.	SE
Basic Design	Around the arm pack the blood cuff	Around the arm under the blood cuff	Analysis 1
Materials	Tyvck/Polyethylene	Polyethylene /Medical grade paper	Analysis 2
Closuse Method	Velcro/Adhesive Tape	Adhesive Tape	Analysis 3
Size	S, M, L	S, M, L	SE
Single Use	Yes	Yes	SE
Sterile	No	No	SE

Analysis 1

The proposed device has different Design to the predicate device, the current design we used is pack the blood cuff, this way could fix the blood cuff around the arm more steadily during measurement process, so we consider this as the proposed device is SE with the predicate device.

Analysis 2

The proposed device has different materials to the predicate device, this different may causes potential biocompatibility risk, for this risk we conducted the biocompatibility test according to the ISO 10993-5 and ISO 10993-10, the test results showed that the proposed devices did not induce any risk relating to the cytotoxicity, irritation or sensitization.

So we consider this as the proposed device is SE with the predicate device.

Analysis 3

The proposed device has different closure method to the predicate device, but the Velcro has the effect to fix the guard and cuff, so we consider this as the proposed device is SE with the predicate device.

Table 2 Biocompatibility Comparison

ITEM	Proposed Device	Predicate Device	Remark
Cytotoxicity	Under the conditions of the study, not cyteotoxicity effect	Comply with ISO 10993-5	SE
Irritation	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	SE

Sensitization	Under conditions of the study, not a sensitizer.		SE

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.